510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92

The assigned 510(k) number is: K110738

Company/Contact person

Lisa Charter
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Date Prepared

October 31, 2011

Regulatory Declarations

Common / Usual Name	MAS® Omni•CORE
Trade/ Proprietary Name	Thermo Scientific MAS® Omni•CORE
Classification Regulation	21 CFR 862.1660 – Quality control material (assayed and unassayed)
Device Class	Class I
Device Regulation Panel	Clinical Chemistry
Product Code	JJY

Intended use

Thermo Scientific MAS® Omni•CORE™ is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include **MAS® Omni•CORE** with patient serum specimens when assaying for any of the constituents. Assay values are provided for the specific systems listed. The user can compare observations with their expected ranges as a means of assuring consistent performance of reagent and instrument.

Legally marketed device to which equivalency is claimed

MAS® Omni•CORE is substantially equivalent to the previously cleared MAS® Chem-TRAK H (K092051) and MAS® Immunology (K960824) Controls.

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Description of Device

Omni•CORE is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various animal extracts and non-protein materials including drugs, drug metabolites and purified chemicals. Amylase, ALT/GPT, AST/GOT, CK and Lipase are obtained from porcine tissue; alkaline phosphatase and GGT are from bovine tissue; LDH is from avian tissue. Preservatives and stabilizers are added to maintain product integrity.

The control is offered in three levels with the following configuration:

MAS® Omni•CORE		
Catalog Number	**Description**	**Size**
OCORE-101	Level 1	6 vials of Level 1, 5 mLs per vial
OCORE-202	Level 2	6 vials of Level 2, 5 mLs per vial
OCORE-303	Level 3	6 vials of Level 3, 5 mLs per vial
OCORE-SP	Sample-pack	1 vial of Level 1, 5 mLs per vial 1 vial of Level 2, 5 mLs per vial 1 vial of Level 3, 5 mLs per vial

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Comparison of Technological Characteristics

Comparison	Subject Device	Predicate 1	Predicate 2
Device	MAS® Omni•CORE	MAS® ChemTRAK H	MAS® Immunology Control
510(k) number	K110738	K092051	K960824
Intended Use	**Thermo Scientific MAS® Omni•CORE™** is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include **MAS® Omni•CORE** with patient serum specimens when assaying for any of the constituents. Assay values are provided for the specific systems listed. The user can compare observations with their expected ranges as a means of assuring consistent performance of reagent and instrument.	chemTRAK® H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include chemTRAK® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument. Moni-Trol® H is intended for use as a consistent test sample of known concentration for monitoring assay conditions in many clinical laboratory determinations. Include Moni-Trol® H with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.	Immunology Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many immunological determinations. Include Immunology control with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.
Matrix	Human Serum	Human Serum	Human Serum
Form	Frozen Liquid	Frozen Liquid	Liquid
Control Levels	Level 1 Level 2 Level 3	Level 1 Level 2 Level 3	Level 1 Level 2 Level 3
Storage	-20°C	-20°C	2-8°C
Shelf Life	3 years	2.5 year	2 years
Analytes by Configuration	Acetaminophen Albumin ALK Phos. (Alkaline Phosphatase) alpha-1-Acid Glycoprotein alpha-1-Antitrypsin alpha-2-Macroglobulin ALT	Acetaminophen Acid Phosphatase* Albumin Alkaline Phosphatase, ALP Alanine Aminotransferase, ALT Alpha-Fetoprotein, AFP* Amikacin	Albumin alpha-1-Acid Glycoprotein alpha-1-Antitrypsin alpha-2-Macroglobulin Antistreptolysin Antithrombin III Apolipoprotein A

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	Amikacin	Amylase	Apolipoprotein B
	Amylase	Apolipoprotein A (APO A)	Beta 2 Microglobulin
	Antistreptolysin O (ASO)	Apolipoprotein B (APO B)	C3 Complement
	Apolipoprotein A1	Aspartate Aminotransferase, AST	C4 Complement
	Apolipoprotein B	Bilirubin, Direct	Ceruloplasmin
	AST	Bilirubin, Total	C-Reactive Protein
	Beta 2 Microglobulin	Blood Urea Nitrogen, BUN	Haptoglobin
	Bile Acids	C3 Complement*	Immunoglobulin A
	Bilirubin, Direct (DBIL)	C4 Complement*	Immunoglobulin E
	Bilirubin, Total (BILT)	Caffeine	Immunoglobulin G
	BUN	Calcium	Immunoglobulin M
	C3 Complement	Carbamazepine	Kappa Light Chain
	C4 Complement	Chloride	Lamda Light Cha
	Caffeine	Cholesterol	Prealbumin
	Calcium	Creatine Kinase, CK	Properidin Factor B
	Carbamazepine	CO_2	Rheumatoid Factor
	Ceruloplasmin	C-Reactive Protein, CRP*	Total Protein
	Chloride	Creatinine	Transferrin
	Cholesterol	Digoxin	
	CK	Disopyramide	
	CO2	Ethanol	
	Copper	Ethosuximide	
	Cortisol	Ferritin*	
	C-Reactive Protein (CRP)	Gentamicin	
	Creatinine	Gamma Glutamyltransferase, GGT	
	Digoxin	Glucose	
	Disoprymide	Glutamate Dehydrogenase, GLDH*	
	Ethanol	Haptoglobin*	
	Ethosuximide	Hydroxybutyrate Dehydrogenase, HBDH*	
	Ferritin	High Density Lipoprotein Cholesterol, HDL	
	Gentamicin	Human Chorionic Gonadotrophin, hCG*	
	GGT	Immunoglobulin A, IgA*	
	Glucose	Immunoglobulin G, IgG*	
	Haptoglobin	Immunoglobulin M, IgM*	
	HDL Cholesterol	Iron	
	IgA	Iron Binding Capacity, Total	
	IgE	Lactic Acid	
	IgG	LDH	
	IgM	LDL-Cholesterol	
	Iron	Lidocaine	

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	Iron Binding Capacity, Total (TIBC) Lactic Acid LDH LDL-Cholesterol Lidocaine Lipase Lipoprotein (a) Lithium Magnesium Methotrexate NAPA Osmolality Phenobarbital Phenytoin Phosphorus Potassium Prealbumin Primidone Procainamide Pseudocholinesterase (PCHE) Quinidine Rheumatoid Factor (RF) Salicylate Sodium Thyroxine, Total T4 Theophylline Thyroid Stimulating Hormone, TSH Tobramycin Total Protein Transferrin Triglycerides Tricyclic Antidepressants (TCA) T-Uptake Unsaturated Iron Binding Capacity (UIBC) Uric Acid Valproic Acid Vancomycin Zinc	Lipase Lipoprotein (LpA) Lithium Magnesium Methotrexate N-Acetylprocainamide, NAPA Osmolality Phenobarbital Phenytoin Phosphorus Potassium Prealbumin Primidone Procainamide Pseudocholinesterase Quinidine Salicylate Sodium Thyroxine Free T4* Thyroxine, Total T4 Theophylline Thyroid Stimulating Hormone, TSH Tobramycin Total Protein Transferrin* Triglycerides Tricyclic Antidepressants Thiiodothyronine, Total T3* Thiiodothyronine Free T3* T-Uptake Unsaturated Iron Binding Capacity (UIBC)* Uric Acid Valproic Acid Vancomycin	

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Conclusion

As summarized, Omni•CORE is substantially equivalent to the previously cleared MAS® Chem-TRAK H (K092051) and MAS Immunology (K960824) Controls. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 03 2011

Microgenics Corporation
c/o Ms. Lisa Charter
Manager, Regulatory Affairs
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Re: k110738
Trade Name: Thermo Scientific MAS® Omni-Core
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, Reserved
Product Codes: JJY
Dated: September 15, 2011
Received: September 20, 2011

Dear Ms. Charter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K110738

Device Name: MAS® Omni•CORE

Indication for Use:

Thermo Scientific MAS® Omni•CORE™ is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include **MAS® Omni•CORE** with patient serum specimens when assaying for any of the constituents. Assay values are provided for the specific systems listed. The user can compare observations with their expected ranges as a means of assuring consistent performance of reagent and instrument.

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110738